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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

	Application No.	Applicant(s)			
	10/799,431	CHAO ET AL.			
Office Action Summary	Examiner	Art Unit			
	Jeffrey T. Palenik	1615			
The MAILING DATE of this communication app Period for Reply	ears on the cover sheet with the c	orrespondence address			
A SHORTENED STATUTORY PERIOD FOR REPLY WHICHEVER IS LONGER, FROM THE MAILING DA  - Extensions of time may be available under the provisions of 37 CFR 1.13 after SIX (6) MONTHS from the mailing date of this communication.  - If NO period for reply is specified above, the maximum statutory period w  - Failure to reply within the set or extended period for reply will, by statute, Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b).	ATE OF THIS COMMUNICATION 36(a). In no event, however, may a reply be tim vill apply and will expire SIX (6) MONTHS from cause the application to become ABANDONE	N. nely filed the mailing date of this communication. D (35 U.S.C. § 133).			
Status					
Responsive to communication(s) filed on <u>09 Jules</u> This action is <b>FINAL</b> . 2b) ☑ This Since this application is in condition for alloward closed in accordance with the practice under E	action is non-final. nce except for formal matters, pro				
Disposition of Claims					
4) ☐ Claim(s) 1-31 is/are pending in the application. 4a) Of the above claim(s) 23-30 is/are withdraw 5) ☐ Claim(s) is/are allowed. 6) ☐ Claim(s) 1-22 and 31 is/are rejected. 7) ☐ Claim(s) 8,9 and 31 is/are objected to. 8) ☐ Claim(s) are subject to restriction and/or Application Papers 9) ☐ The specification is objected to by the Examiner 10) ☐ The drawing(s) filed on is/are: a) ☐ access that any objection to the objected to applicant may not request that any objected to applicant may not request that any objected to applicant may not request the appl	r election requirement. r. epted or b)  objected to by the B	e 37 CFR 1.85(a).			
11)☐ The oath or declaration is objected to by the Ex	aminer. Note the attached Office	Action or form PTO-152.			
Priority under 35 U.S.C. § 119					
<ul> <li>12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).</li> <li>a) All b) Some * c) None of:</li> <li>1. Certified copies of the priority documents have been received.</li> <li>2. Certified copies of the priority documents have been received in Application No</li> <li>3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).</li> <li>* See the attached detailed Office action for a list of the certified copies not received.</li> </ul>					
Attachment(s)  1) Notice of References Cited (PTO-892)  2) Notice of Draftsperson's Patent Drawing Review (PTO-948)  3) Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date	4) Interview Summary Paper No(s)/Mail Da 5) Notice of Informal P 6) Other:	ate			

#### **DETAILED ACTION**

#### STATUS OF THE APPLICATION

Receipt is acknowledged of Applicants' timely filed Amendments and Remarks of 9 June 2009. Said remarks and amendments are entered on the record. The Examiner further acknowledges the following:

Claims 1-31 are now pending with claim 31 being newly added and claims 23-30 remaining withdrawn from consideration. No claims have been cancelled.

The addition of claim 31 is supported by the instant disclosure (see Examples).

Claims 2, 6, 8, 10 have been amended and support provided.

No new matter has been added.

As such, claims 1-22 and 31 now represent all claims currently under consideration.

### Information Disclosure Statement

No new Information Disclosure Statements (IDS) have been submitted for review or consideration.

#### WITHDRAWN OBJECTIONS/REJECTIONS

# Rejection under 35 USC 103(a)

Applicants' remarks have been fully considered and are sufficient to render moot the rejection to claims 1-22, under 35 USC 103(a), as being unpatentable over the combined teachings of Chapin et al. in view of Riew et al. Applicants persuasively argue the combined references on the basis of their divergent technologies. Since the combination of references is no longer considered as reading on the limitations, said rejection now stands **withdrawn**.

## MAINTAINED OBJECTION/REJECTIONS

The following rejections are maintained from the previous Office Correspondence dated 15 October 2008 since the art which was previously cited continues to read on the limitations.

### CLAIM REJECTIONS - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 6, 10-16 and 18-22 are rejected under 35 U.S.C. 102(b) as being anticipated by Chapin et al. (USPN 4,594,380).

The instant claims are directed to a continuous-release composition comprising an elastomeric matrix and at least one active agent wherein said matrix is the reaction product of a carboxyl-terminated polymer and a polycarbodiimide (claims 1, 2, 6, 10-12, 14 and 22). With regard to the limitation of claim 1, wherein "the active agent being released from the matrix into the environment substantially continuously over an extended period of time", is considered by the Examiner as a functional limitation of the instantly claimed composition; it is a limitation expected of a continuous release composition. With regard to the limitations respectively recited in claims 2 and 6, which state "wherein the ratio of polycarbodiimide to carboxyl-terminated polymer is 0.7 to 6.0" and "...is 0.7 to 1.4", until some material difference(s) in the properties of the composition are demonstrated, said limitation is considered by the Examiner to be directed toward the elastomeric matrix composition which is instantly claimed. Regarding the limitation

of claims 10-12 wherein the carboxyl terminated copolymer of claim 1 is the reaction product of a mixture...", is deemed by the Examiner as being a product-by-process limitation, which per MPEP §2113, holds no patentable weight. Regarding the limitations recited in claims 11 and 12 which are directed to the percent composition of the carboxyl-terminated copolymer, said recitations are deemed by the Examiner as being functional limitations to product-by-process limitations and similarly hold no patentable weight. The functionality limitation as recited in claim 14, is considered an inseparable property of the polycarbodiimide component of the matrix composition (see MPEP §2112.01(II)). The limitation "in the form of a gel" recited in claim 22 is deemed one of intended use and holds no patentable weight with regards to the instantly claimed composition. Hydrophobic carboxyl-terminated polymers are recited (claim 3). Types of polycarbodiimides used are recited (claim 13). The composition further comprising one or more inert (e.g. non-biologically active) agents is recited (claims 15 and 16). Dissolution or dispersal of the active agent(s) in the matrix is recited (claims 18 and 19). Percentage of the active(s) in the matrix is recited (claim 20). A fragrance as the active agent(s) is recited (claim 21).

Chapin et al. teach an article comprising an elastomeric matrix and at least one biologically or non-biologically active agent in the matrix which is continuously released over an extended period of time (claim 1). Said matrix is taught as comprising polyurethane which is formed by reacting a polyol with an isocyanate (claim 1). Though the term "polycarbodiimide" is not expressly used in the teachings of Chapin, the polyurethane which is formed from the reaction of Chapin in claim 1, is polycarbodiimide as defined by Torimae et al. (USPN 4,221,572) wherein the toluene diisocyanate and polyols are reacted to form polycarbodiimide

compounds (Abstract and Example 1). The same reaction is performed by Chapin wherein the reacted polyol comprises hydroxyl-terminated and carboxyl-terminated components and the isocyanates used comprise aromatic, aliphatic, cycloaliphatic and heterocyclic isocyanates having functionalities greater than 2 (e.g. between 2 and 3) (claims 1 and 2). The instantly claimed hydrophobic carboxyl-terminated polymers are taught in claim 2. The polyol taught in claim 1 is taught as a copolymer of hydroxyl- and carboxyl-terminated polymers, the resulting copolymer having a molecular weight ranging from 400-10,000. Claim 3 teaches the composition as further comprising inert components such as fillers, plasticizers, stabilizers, pigments and fungicides. Claim 4 teaches fragrances (e.g. deodorants, air fresheners, perfumes, attractants and repellents) as the active agent. Claims 9 and 10 respectively teach the active agent as being dissolved and dispersed in the matrix. Claim 8 teaches the active agent as comprising 10-50% by weight of the article.

## RESPONSE TO ARGUMENTS

Applicants' arguments with regard to the rejection of claims 1-3, 6, 10-16 and 18-22 under 35 USC 102(b) as being anticipated by Chapin et a. (USPN 4,594,380), has been fully considered, but is not persuasive.

Applicants argue that the composition prepared by Chapin is a polyurethane which is made by reaction of a polyol with a polyisocyanate and that Chapin does not disclose a polycarbodiimide. Applicants further state on the record that "[a] polycarbodiimide is typically prepared by polymerizing a polyisocyanate itself, such as toluene diisocyanate or diphenyl methane diisocyanate".

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In response, the Examiner respectfully disagrees submits that the composition which is taught as being prepared in claims 1 and 2 of Chapin is considered as reading on the composition recited by the instant base claim. Claim 1 of Chapin teaches an article comprising an elastomeric matrix and at least one active agent contained within the matrix, wherein said matrix is prepared by reacting a polyol with *an* isocyanate [*emphasis added*]. Chapin further defines and sets forth preferred isocyanates as being polyarylene isocyanates which are taught further still as being prepared from aromatic isocyanates such as 2,4 toluene diisocyanate, and 2,6 toluene diisocyanate, mixtures thereof, and 4,4' diphenyl methane diisocyanate and its oligomers (col. 5, lines 50-56). Diisocyanates, such as the aforementioned, are well known in the art as being used to produce preferred unhindered aromatic polycarbodiimides. See for example Brown et al. (USPN 3,835,098; col. 4, lines 14-40).

Thus, for these reasons, Applicants' arguments are found unpersuasive. The above rejection is hereby **maintained**.

#### **NEW REJECTIONS**

In light of Applicants' remarks, the withdrawn rejection discussed above, as well as the addition of new claim 31, the following rejections have been newly added:

# CLAIM REJECTIONS - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 8 and 9 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter that is not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. Claim 1 is drawn to a continuous release composition comprising an elastomeric matrix which is the reaction product of a polycarbodiimide and a carboxyl-terminated polymer. Claim 8 further limits said carboxyl-terminated polymer to carboxyl-terminated polyethylene oxides and carboxyl-terminated polyether polyols. While the Examiner acknowledges that "carboxylterminated polyether polyols" are discussed in ¶0018] the instant specification, the term is not defined by the instant specification in a clear and concise manner. Applicants do further limit their discussion of hydrophilic carboxyl-terminated polymers in the Examples as reacting specific hydroxyl-terminated polyols with anhydride compounds. Said polyol compounds are described as being poly(ethylene glycol) of different molecular weights as well as Polyol TP 200 and Polyol PP 150. The compound "Polyol TP 200" is known in the art as ethoxylated trimethylolpropane (see attached product safety data sheet form Perstorp) which has the following structure:

ethoxyl trimethylolpropane

However, no such data, description or structure has been found in the art regarding "Polyol PP 150". The only description provided by Applicants in ¶[0052] regarding this compound is that it has 4-OH groups and that it is also provided by Perstorp. As such, the disclosure of the instant specification is not sufficient to support the generic concept of "carboxyl-terminated polyether polyols" and requires further clarification. As it is difficult to construe a clear definition from the prior art, the Examiner makes the following request in order to provide clarification on the record:

# REQUEST FOR INFORMATION

Applicant and the assignee of this application are required under 37 CFR 1.105 to provide the following information that the examiner has determined is reasonably necessary to the examination of this application.

The information is required to identify products and services embodying the disclosed subject matter of the exemplified commercial hydroxyl-terminated polyol designated "Polyol PP 150" by Perstorp (see pg. 11, ¶[0052] of the specification) and identify the properties of similar products and services found in the prior art. A search through the instant application reveals that the "Polyol PP 150" compound appears to be a particular species of hydrophilic hydroxyl-terminated polymer, which when admixed with an anhydride compound provides the inventive hydrophilic carboxyl-terminated polymer. However, no specific formula or information is disclosed regarding these materials.

In response to this requirement, please provide the title, citation and copy of each publication that any of the Applicants relied upon to draft the claimed subject matter. For each

publication, please provide a concise explanation of the reliance placed on that publication in distinguishing the claimed subject matter from the prior art.

In response to this requirement, please provide the names of any products or services that have incorporated the claimed subject matter.

The Applicants are reminded that the reply to this requirement must be made with candor and good faith under 37 CFR 1.56. Where the applicant does not have or cannot readily obtain an item of required information, a statement that the item is unknown or cannot be readily obtained may be accepted as a complete reply to the requirement for that item.

This requirement is subject to the provisions of 37 CFR 1.134, 1.135 and 1.136 and has a shortened statutory period of 2 months. EXTENSIONS OF THIS TIME PERIOD MAY BE GRANTED UNDER 37 CFR 1.136(a).

Claims 1-22 and 31 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a limited carboxyl-terminated polymers, such as those set forth in ¶¶[0017] and [0018] of the instant specification, does not reasonably provide enablement for the generic class of carboxyl-terminated polymers which may be coupled with polycarbodiimide to form elastomeric matrices. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims. The limitation "a carboxyl-terminated polymer" is extremely broad and encompasses a larger class of compounds than that which is instantly discussed. Given its broadest reasonable interpretation, "a carboxyl-terminated polymer" refers to *any* polymer which is terminated or "capped" with a carboxylic acid

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functional group. Within this general class of polymers reside sub-classes of polymers such as step-growth or "condensation" polymers as well as chain-growth or "addition" polymers. The "addition" polymers are class of polymers for which Applicants provide support. The specification clearly discusses incorporating hydrophilic carboxyl-terminated polyethylene oxides and CT polyether polyols as well as hydrophobic isoprene- and butadiene-based addition polymers. However, the instant disclosure does not reasonably provide the ordinarily skilled artisan any discussion or description regarding the production of the instantly claimed activeloaded, elastomeric matrices wherein polycarbodiimides are reacted with "condensation" polymers such as polyamides and polyesters. To this end, given that the instant invention is drawn to a elastomeric composition which delivers active agents produced from seemingly particular narrow classes of compounds, the Examiner respectfully submits that one of ordinary skill in the art would be faced with an undue experimental burden in attempting to practice the invention commensurate in scope with the claims. That is, the instant invention is concerned with only a very limited subclass of carboxyl-terminated polymers, such as the ones set forth in ¶¶[0017] and [0018], and more narrowly still, those CT polymers which are mentioned in the Examples of the instant specification. It thus follows that the ordinarily skilled practitioner would need to undergo undue experimentation in order to develop and arrive at a thermoplastic and elastomeric matrix composition capable of delivering an active agent without seeking guidance from the prior art. As such, the disclosure of the instant specification is not sufficient to support the generic concept of "a matrix formed from the reaction of a polycarbodiimide and a carboxyl-terminated polymer" on the grounds of the carboxyl-terminated polymer.

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The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 4, 5, 8 and 9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding the recitations of the carboxyl-terminated polymer, whether in the hydrophobic (claims 4 and 5) or hydrophilic (claims 8 and 9) form, said recitations are rendered indefinite where they are further limited by the term "a major component". Claims 4 and 8 recite that the carboxyl-terminated polymer is hydrophobic/hydrophilic and "a major component" is selected from one of two respective lists of compounds. Based on said recitations, it is not clear to the Examiner what Applicants' intended use of the term is directed to. As interpreted from the claims, the Examiner broadly and reasonably construes the term as possibly being "a major component" of the elastomeric matrix, the composition which comprises said matrix or the carboxyl-terminated polymer itself. Interpreting the term in light of Applicants' instant disclosure (MPEP 2111), the Examiner broadly and reasonably interprets the claims as reciting that the carboxyl-terminated polymer is either hydrophobic or hydrophilic and <u>is</u> one of the recited compounds [emphasis added]. Paragraph [0017], which offers the best definition, states that "the major component typically makes up at least 90% by weight of the polyacid [(e.g. carboxyl-terminated polymer)] and is selected from the group consisting of carboxyl-terminated compounds...". Turning to Applicants' Examples, it is clear that the skilled artisan practicing this invention is required to *prepare* the instantly claimed carboxyl-terminated polymers from an anhydride compound and hydroxyl-terminated polymer such as a polyol, PEG or polybutadiene

compound. As such, for the purposes of examination on the record the Examiner interprets the claims as reciting that the carboxyl-terminated polymer comprises compounds such as carboxyl-terminated polybutadiene. Regarding the percent by weight limitations (e.g. claim 5), where an elastomeric matrix may be formed using one of the carboxyl-terminated polymers, it will thus be broadly and reasonably interpreted by the Examiner as reading on "at least 90% of the polymer".

# CLAIM REJECTIONS - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 4, 5, 7 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over the teachings of Chapin with respect to claim 1 as set forth above.

The instant invention is drawn to a continuous release composition comprising an elastomeric matrix which is the reaction product of a carboxyl-terminated polymer and a polycarbodiimide, as discussed above. Also as discussed above, claims 4 and 5 recite that said carboxyl-terminated polymer is both hydrophobic and selected from a group of polymers such as carboxyl-terminated polybutadiene and carboxyl-terminated copolymers of polybutadiene with acrylonitrile and that said polymers represent at least 90% by weight of the carboxyl-terminated polymer. Claims 7 and 17 each further limit the carboxyl-terminated polymer of claim 1 in terms of its molecular weight, ranging from 1,000 to 20,000 and 1,000 to 10,000, respectively. Claim 17 further recites that the carboxyl-terminated polymer has an average carboxylic acid functionality ranging from 1.8-8.0. With regard to the functionality limitation recited in claim 17; until some material difference(s) in the properties of the composition are demonstrated, said limitation is considered by the Examiner to be directed toward the instantly claimed carboxyl-terminated polymer having a molecular weight which reads on the instantly claimed weight range.

The teachings of Chapin are discussed above. Chapin further teaches that the polyurethane elastomer is formed using a process which reacts polyols with isocyanates, wherein carboxyl-terminated polymers are expressly taught as optional minor components (col. 3, lines 7-10 and lines 18-26). The compounds which are expressly taught by the passage read on those which are recited in claim 4. Said carboxyl-terminated polymers are taught as having a molecular weight ranging from 400 to 10,000, which teaches the limitations of claims 7 and 17. The "major component" limitations, as discussed above with regards to claims 4 and 5, are considered as being expressly taught by the passage.

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Thus, in view of the express teachings provided by Chapin, it would have been prima facie obvious to a person of ordinary skill in the art at the time of the invention to have prepared a polyurethane elastomer by mixing a carboxyl-terminated polymer with an isocyanate in order to achieve the instantly claimed composition. The ordinarily skilled artisan would have been highly motivated to do so particularly in view of two points. First, the aforementioned discussion of the term "isocyanate" per Chapin preferably teaches that such a compound includes polymers, oligomers and mixtures of 2,4- and 2,6-toluene diisocyanate, and diphenyl methane diisocyanate compounds. As discussed above, polymerization of such compounds is well known in the art as the formation of polycarbodiimides. Further, per the discussion above regarding the carboxyl-terminated polymer and the indefinite recitation of "a major component", the Examiner interprets said limitation in light of Applicants' disclosure as setting forth that the carboxylterminated polymer comprises at least 90 wt% of compounds such as carboxyl-terminated butadiene or CT copolymers of butadiene with acrylonitrile (see claims 4 and 5). Said compounds are expressly taught by Chapin, albeit as optional compounds, as being available in the art for selection as the carboxyl-terminated polymer. As such, were the skilled artisan to select one of these compounds to prepare the elastomer matrix, it follows that it would comprise 100% of the carboxyl-terminated polymer (e.g. the "major component"). The ordinarily skilled artisan would be motivated further still to incorporate the optional carboxyl-terminated polymers into the elastomer formulation in the interest of altering or adjusting the cross-link density of the final elastomer matrix. Such an adjustment is expressly taught as influencing the ability of the formulation to release the active compound embedded within (col. 5, lines 1-7).

Thus, based on the teachings of the reference, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention.

Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at

the time the invention was made, as evidenced by the references, alone or in combination,

especially in the absence of evidence to the contrary.

ALLOWABLE SUBJECT MATTER

Claims 8, 9 and 31 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, first and second paragraphs, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

Claims 8, 9, and 31 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

The remaining claims remain rejected.

**CONCLUSION** 

Due to the new grounds of rejection, this action is deemed **non-final**.

CORRESPONDENCE

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey T. Palenik whose telephone number is (571) 270-1966. The examiner can normally be reached on 7:30 am - 5:00 pm; M-F (EST).

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jeffrey T. Palenik/ Examiner, Art Unit 1615 /MP WOODWARD/ Supervisory Patent Examiner, Art Unit 1615